UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,943	08/21/2006	Brian E. Jones	GC796-2-US	7104

7590 01/23/2009

Victoria L Boyd
GENENCOR INTERNATIONAL INC
925 Page Mill Road
Palo Alto, CA 94304-1013

EXAMINER	
CHOWDHURY, IQBAL HOSSAIN	

ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
01/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Item 3 (d):

The scope of Claim 2 has been broadened because the deletion of the functional language, and thus, new consideration of the claim is now required. The amendment will not be entered.

Item 11:

Claims 1, 3-5, 7-21, 25-28 and 30 are rejected under 35 U.S.C. 112, first paragraph on scope of enablement issues. This rejection is maintained for the reasons as set forth in the prior office action mailed on 08/19/2008.

Arguments:

1. Applicants argue that the Examiner acknowledges that the specification is enabling for a nucleic acid sequence of SEQ ID NO: 1 or 2, a polypeptide of SEQ ID NO: 3, and expression vectors and detergent compositions comprising the same. Since variant polynucleotides and polypeptides, and polypeptide fragments, are expected to possess similar properties with respect to the respective reference molecules, they are made and used in the same manner as the reference molecules. No additional information is required to make and use the claimed variant polynucleotides and polypeptides, or polypeptide fragments. Therefore, the specification is enabling for polynucleotides and polypeptides commensurate with the full scope of the claims.

2. Applicants' also argue that regarding Guo et al. reference that even assuming that some variants or fragments of the present cellulases would be inactive, this observation, alone, should not result in an enablement rejection. First, the pending claims expressly require cellulase activity, thereby excluding inactive molecules.

Second, the skilled person is by no means "reduced to the necessity of producing and testing virtually all the possibilities" as asserted by the Examiner. The skilled in the art would use the vast amount of knowledge available in the art to make and test variants that are likely to retain cellulase activity. Suggesting that a skilled person would randomly make and test variants ignores the level of skill in the art and how skilled persons design and test polypeptide variants. Since the legal question of enablement considers the level of skill in the art, a rejection based purely on the statistics of random mutagenesis is misplaced. This is simply not how the skilled person would make or test variants.

Response:

Applicants' arguments have been fully considered but are found unpersuasive.

In regard of argument 1, the Examiner finds the arguments unpersuasive because during making those mutants having 15% non-identity allows up to 87 mutations within the 581 amino acids of SEQ ID NO: 3, which does not provide any specific structure having the functional feature. Therefore, one of ordinary skilled in the art will not know how to make the claimed invention having 87 amino acid changed in any combination but retaining functional feature, and to do this, one of ordinary skilled in the art needs to screen many mutants to practice the claimed invention, which would require many undue experimentations.

In regard of argument 2, the Examiner agrees that claims 1, 7, 15 and 25 (and dependent claims) recite functional feature but many unknown structures are encompassed within the scope of the claims in terms of 85% identity, i.e. 15% non-

identity includes 87 amino acids mutation in any combinations as well as fragments, which is not taught by the specification and the prior art (see the sequence search of SEQ ID NO: 3 in the PAIR). The claims are examined based on not only legal consideration but also scientific reasons in terms of molecular biology and statistical considerations.

Therefore, the rejection is maintained.

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Ahsan et al. (Cloning, DNA sequencing, and expression of the gene encoding Clostridium thermocellum cellulase CelJ, the largest catalytic component of the cellulosome, J Bacteriol. 1996 Oct;178(19):5732-40). This rejection is maintained for the reasons as set forth in the prior office action mailed on 08/19/2008.

Arguments:

Applicants argue that the standard for lack of novelty, that is, for anticipation, is one of strict identity and to anticipate a claim for a patent, a single prior source must contain all its essential elements. Ahsan et al. teach a cellulase that shares only 26.2% "best local identity" with SEQ ID NO: 3. There is no teaching in the reference or other evidence of record to suggest that a fragment of SEQ ID NO: 3 that has cellulase activity reads on the sequence of Ahsan et al. Since anticipation requires that a single reference teach all essential elements of a claim, it is clear that Ahsan et al does not anticipate claim 15. In the absence of any specific teaching in the reference, the Examiner's argument appears to be based on inherency. However, it is well-settled law

that inherency can not be established by mere possibilities. In the present case, the Examiner has not established even the mere possibility that a fragment of SEQ ID NO: 3 having cellulase activity would read on the sequence of Ahsan et al.

Response:

Applicant's arguments have been fully considered, but they are not deemed persuasive to overcome the rejection on anticipation issue. Claim 15, part (e) recites "a biologically active fragment of SEQ ID NO: 3" having cellulase activity as biological activity of said fragment, which indicates any fragment of SEQ ID NO: 3 having any structural feature but that fragment must have cellulase activity. Ahsan et al. indeed disclose a cellulase (same biological activity as instant application), which is 26.2% identical (best local similarity) to SEQ ID NO: 3 (see attached sequence alignment) having cellulase activity, i.e. a fragment of amino acid from position 410-419 (10 amino acid long) corresponding to amino acid at position 237-246 of SEQ ID NO: 3 of the instant application reads on the scope of claim 15, wherein said protein has cellulase activity. Therefore, the polypeptide of Ahsan et al. meets the scope of the claim as written, i.e. claims requires "a biologically active fragment of SEQ ID NO: 3" and Ahsan et al. teach a polypeptide within the scope of the claim as written. Therefore, the rejection is maintained.

/Nashaat T. Nashed/
Supervisory Patent Examiner, Art Unit 1652